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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/549,642	04/14/2000	Johan R. de Faire	314572-101F	9183

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[REDACTED] EXAMINER

LUCAS, ZACHARIAH

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1648

DATE MAILED: 11/05/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/549,642	DE FAIRE ET AL.
	Examiner	Art Unit
	Zachariah Lucas	1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 19 August 2002.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 142-144 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 142-144 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1.) Certified copies of the priority documents have been received.
 2.) Certified copies of the priority documents have been received in Application No. _____.
 3.) Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Status of the Claims

1. Currently Claims 142-144 are pending in this application. The claims were the subject of a Notice of Appeal, and Appeal Brief (papers 10 and 12 respectively). For the purpose of reformulating and clarifying the rejections, the finality of the prior Office Action, mailed January 2, 2002, is being withdrawn, and prosecution is reopened with this non-final action.

Specification

2. (**Prior Objection-Maintained**) The specification is objected to for referring to protein or nucleic acid sequences without also identifying them by the sequence identifier assigned to them in the sequence listing as required by 37 CFR 1.821(d). See e.g., pp. 43 and 45. The examiner would like to bring the applicant's attention to the following excerpt from MPEP §2422.03:

37 CFR 1.821(d) requires the use of the assigned sequence identifier in all instances where the description or claims of a patent application discuss sequences regardless of whether a given sequence is also embedded in the text of the description or claims of an application. This requirement is also intended to permit references, in both the description and claims, to sequences set forth in the "Sequence Listing" by the use of assigned sequence identifiers without repeating the sequence in the text of the description or claims. Sequence identifiers can also be used to discuss and/or claim parts or fragments of a properly presented sequence. For example, language such as "residues 14 to 243 of SEQ ID NO: 23" is permissible and the fragment need not be separately presented in the "Sequence Listing." Where a sequence is embedded in the text of an application, it must be presented in a manner that complies with the requirements of the sequence rules.

The applicant is therefore required to amend the specification to comply with 37 CFR 1.821(d).

3. (**Prior Objection- Maintained**) The amendment filed October 3, 2001 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states

that no amendment shall introduce new matter into the disclosure of the invention. Reasoning is for substantially the reasons of record. More particularly, the deleted subject matter includes parts of the specification that describe the enzymes being isolated from the krill and that identify the preferred embodiments of the claimed invention. See e.g., p. 2, lines 3-30; p. 3, lines 1-9; pp. 35 line 22 - p. 38, line 24; and p. 40, lines 10-30. It is further noted that in the remaining portion of the specification (p. 69, lines 27-28, and p. 70, line10), and in the Appeal Brief (page 3- implying that the present application teaches how much of the composition to apply), still refers to cancelled subject matter. See, Example 1A, cancelled by Amendment B (filed October 3, 2001, in Appendix B1, page 3). Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Objections

4. **(Prior Objection- Maintained)** Claim 144 is objected to because of the following informality. In line 2 of the claim, the term “not” should read “no.”

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. **(Prior Rejection- Maintained)** Claims 142-144 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the

application was filed, had possession of the claimed invention. Claims 143 and 144 describes the limitation to the claimed methods, respectively, as follows: “wherein the dental plaque is visually observable,” and “wherein the contacting is conducted or repeated until dental plaque is no longer visually observable.” In the Appeal Brief, at pages 7-8, the applicant argues that there is clearly support for the phrase “wherein the dental plaque is visually observable.” The examiner agrees that this statement has support as amply identified by the applicant in the appeal brief.

However, that phrase is not the focus of the rejection. It is merely the basis for the problematic phrase of claim 144 wherein the “the contacting is conducted or repeated until the dental plaque is no longer visually observable.” This phrase opens the claim to not merely a single contacting of the dental plaque, but an infinite number of such contacts until such time that the plaque is no longer visible. There is no support for such open-ended language in the specification. The specification in the application explicitly states that the treatment may not continue “for longer than 7 days.” Page 70, lines 16-18. Thus, the specification lacks written description for treatment for any period that extends beyond seven days.

Claim Rejections - 35 USC §§ 102 and 103

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. (**Prior Rejection- Withdrawn**) Claims 142-144 were rejected in the prior action under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Hellgren et al. This rejection is withdrawn because while the office finds this reference to be relevant to the patentability of the claimed methods, the reference is more properly applicable as and reference under 35 U.S.C. 103(a) in combination with the Ratcliff and Karlstam references which formerly formed the basis of a 103(a) rejection in the absence of this rejection. The applicant's arguments that are still relevant will be addressed in the discussion of the reformulated rejection below.

10. (**Prior Rejection-Withdrawn**) Claims 142-144 were rejected in the prior action under 35 U.S.C. 103(a) as being unpatentable over Karlstam in view of Ratcliff. This rejection is withdrawn so that the rejection may be reformulated with these two references in combination with the Hellgren reference above. As the reference is no longer being applied under 35 U.S.C. 102, the applicant's arguments concerning this part of the rejection are moot. The applicant's arguments that are still relevant will be addressed in the discussion of the reformulated rejection below.

11. **(New Rejection)** Claims 142-144 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ratcliff (U.S. Patent 4,837,009), in view of Hellgren (U.S. Patent 4,963,491) and Karlstam (EPA 0257003). The claims read on methods of removing dental plaque from teeth in an animal subject by contacting the plaque with an effective amount of hydrolase mixture comprising krill enzymes. The defendant claims add the limitations that the dental plaque be visually observable, and that the contacting be continued until such time as the plaque is no longer visually observable.

Ratcliff teaches a composition for the reduction, prevention, and treatment of oral diseases involving plaque. The reference teaches that glycoproteins play an important part in bacterial agglutination in the mouth. Col. 3, lines 30-47. The patent further teaches that bacterial agglutination comprises a complex matrix of glucosamineglycans, proteoglycans, glycoproteins, sugar, proteins, and lipids. Col. 3, line 62-col. 4, line 6. Ratcliff also teaches a composition (ClO_2) capable of breaking down the matrix components, and thereby help in the removal and prevention of dental plaque. Col. 4, lines 10-23. However, Ratcliff neither teaches nor suggests the use of krill derived enzymes to treat or prevent bacterial agglutination.

Hellgren teaches that krill comprise of a number of different enzymes, including proteinases, peptidases, lipases, phospholipases, and carbohydrate degrading enzymes. Col. 1, lines 47-63. The reference also teaches that composition comprising these enzymes is usable to remove biological contaminant from living or dead tissue. Col. 4, lines 3-23. The reference states the treatment to remove such biological contaminants with the composition should be continued for a sufficient period of time to allow for the degradation of the contaminants, and that it may be repeated (thereby meeting the requirements of claims 143 and 144, as a visual inspection would

have been obvious to one of ordinary skill in the art). Col. 4, lines 24-28. Finally, among the materials for which the composition is suggested as being useful for cleaning are teeth. Col. 1, line 31. This reference therefore suggests that a composition comprising krill derived enzymes may be used for the cleaning of teeth, and more particular for the removal of biological contaminants from teeth. However, the reference does not teach or suggest that the composition may be used to treat or remove dental plaque.

Karlstrom teaches a krill derived enzyme that is usable to degrade a particular glycosaminoglycan. Abstract, and page 2. See also, On-Line Medical Dictionary, CancerWEB 1997-2002 (definition for glycosaminoglycan, and indication that glucosaminoglycan is another word for the same type of molecule). The patent also teaches that the enzyme may be used in a number of therapeutic treatments. However, the application does not teach the use of the enzyme to degrade plaque.

One of ordinary skill in the art would know from the combination of Karlstrom and Hellgren that enzymes derived from Krill has many therapeutic uses including both the cleaning of teeth, and the use in therapeutic treatments. The references also tell one of ordinary skill in the art that compositions comprising these enzymes may be used to clean teeth, and to remove biological contaminant from the same. Hellgren also describes a method of use that includes repeated contact of the contaminant to be cleaned with the composition. Both Karlstrom and Hellgren identify the enzymes as enzymes capable of degrading the components of the bacterial agglutination matrix taught by Ratcliff. Further, as these enzymes are capable of degrading the same components that are taught by Ratcliff as being targeted by the composition Ratcliff used to degrade plaque, one of ordinary skill in the art would have both been motivated to use, and

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had a reasonable expectation of success in the use of the krill enzymes to target dental plaque. As dental plaque may also be considered a biological contaminant and it is on teeth, the combination of Hellgren and Ratcliff clearly provide additional motivation to those of ordinary skill in the art to use the composition of Hellgren to remove dental plaque.

In the Appeal Brief, the applicants argue that Hellgren does not, alone, teach that the krill enzyme composition may be used, or would be effective in the removal of, dental plaque. Appeal Brief, pages 3-5. The examiner believes that the above relationship between Ratcliff and Hellgren would have adequately motivated one of ordinary skill in the art to so use the enzyme composition and provides a basis for a reasonable expectation of success in so using the composition.

The applicant further argues that the combination of Karlstam and Ratcliff do not suggest the use of krill enzymes to remove plaque. Appeal Brief, pages 6-7. However, even if there is not adequate connection between Karlstam and Ratcliff to motivate the use of the Karlstam/Hellgren enzymes in the stead of the ClO₂ of Ratcliff, the examiner believes that the addition of the Hellgren reference to the other two references completes the rejection for the reasons stated above.

Conclusion

12. No claims are allowed.

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13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 703-308-4240. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Z. Lucas
Patent Examiner
October 29, 2002

James C. Housel
JAMES HOUSEL 11/3/02
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